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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,259

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Ralph B. Lilly

Anon-001:C

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EXAMINER

NAJARIAN, LENA

ART UNIT

PAPER NUMBER

3686

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,259	Applicant(s) LILLY ET AL.	
	Examiner LENA NAJARIAN	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-10 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 10/30/09. Claims 1-4, 6-9, and 22-24 have been amended. Claims 5 and 11-21 have been cancelled. Claims 1-4, 6-10, and 22-24 are pending.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-4, 6-10, and 22-24 under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to the amendment filed 10/30/09.

Claim Rejections - 35 USC § 101

3. The rejection of claims 1-4, 6-10, and 22-24 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 10/30/09.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 6-10 and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Denny (US 6,687,676 B1).

(A) Referring to claim 1, Cunningham discloses a method for controlling a computer system for tracking prescriptive medication, to address and control prescription drug abuse, the computer system comprising a processor and a connection between the processor and a plurality of entities, the entities having pharmaceutical data related to prescriptive medication purchases by a plurality of purchasers from a time of the connection between the processor and the entity, said method comprising (abstract, Fig. 1, and col. 3, lines 54-56 of Cunningham):

providing connections from the processor to the plurality of entities, said plurality of entities comprising a plurality of affiliated pharmacies (Fig. 1, col. 3, lines 4-10, and col. 4, lines 37-62 of Cunningham);

obtaining and storing the pharmaceutical data related to the prescriptive medication purchases by the purchasers from said plurality of entities (col. 2, line 64 – col. 3, line 10 & col. 3, lines 40-67 of Cunningham; the Examiner interprets the "patients" to be a form of "purchasers"); and

selectively transferring said pharmaceutical data through said connections to at least one of said plurality of entities for obtaining a prescriptive history of the purchaser based on the pharmaceutical data (col. 3, lines 4-10 and col. 3, lines 54-67 of Cunningham).

Cunningham does not expressly disclose unaffiliated pharmacies and that a complete prescriptive history comprises all prescriptive medications purchased in the aggregate by the purchaser from all of said plurality of entities and generating via the processor from said complete prescriptive history of the purchaser one or more patterns which flag prescriptive drug abuse.

Denny discloses unaffiliated pharmacies and that a complete prescriptive history comprises all prescriptive medications purchased in the aggregate by the purchaser from all of said plurality of entities and generating via the processor from said complete prescriptive history of the purchaser one or more patterns which flag prescriptive drug abuse (Fig. 7, col. 3, lines 20-37, col. 4, lines 30-46, col. 6, lines 37-51, and col. 11, line 58 - col. 12, line 20 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

(B) Referring to claim 2, Cunningham discloses providing that said at least one of said plurality of entities comprises a physician's office and the purchaser is a patient of said physician (col. 2, lines 40-44 and col. 6, lines 44-61 of Cunningham); and

said prescriber utilizing said pharmaceutical data (Fig. 1 of Cunningham).

Cunningham does not expressly disclose that the physician's office verifies said complete prescriptive history of the purchaser.

Denny discloses the physician verifying said complete prescriptive history of the purchaser (see abstract and col. 6, lines 37-51 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

(C) Referring to claim 3, Cunningham discloses providing that said at least one of said plurality of entities comprises a pharmacy with a pharmacist (col. 11, lines 38-40 of Cunningham);

the purchaser requesting that said pharmacist fill a new prescriptive medication (col. 3, lines 54-57 of Cunningham); and

said pharmacist utilizing said pharmaceutical data to compare said new prescriptive medication with respect to said complete prescriptive history of the purchaser (col. 3, lines 54-67 of Cunningham).

(D) Referring to claim 4, Cunningham discloses said pharmacist accepting or declining to fill said new prescriptive medication based on said complete prescriptive history (col. 3, lines 54-67 of Cunningham).

(E) Referring to claim 6, Cunningham does not expressly disclose providing that at least one of said plurality of entities comprises a hospital and the purchaser is a patient of said hospital; and said hospital utilizing said pharmaceutical data to determine said complete prescriptive history of the purchaser.

Denny discloses providing that at least one of said plurality of entities comprises a hospital and the purchaser is a patient of said hospital (col. 3, lines 20-37 and col. 4, lines 30-46 of Denny); and said hospital utilizing said pharmaceutical data to determine said complete prescriptive history of the purchaser (col. 6, lines 27-51 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

(F) Referring to claim 7, Cunningham discloses providing that said pharmaceutical data for each of said prescriptive medication purchases comprises a name of the purchaser, a drug prescribed, a quantity of said drug, a dosage of said drug, a pharmacist name, and a doctor name (col. 5, lines 16-60 and col. 6, lines 6-25 of Cunningham).

Cunningham does not disclose an address of the purchaser.

Denny discloses an address of the purchaser (col. 8, lines 41-53 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Denny within Cunningham. The motivation for doing so would have been to have complete patient information (col. 8, lines 41-53 of Denny).

(G) Referring to claim 8, Cunningham does not disclose searching the pharmaceutical data based on one or more of said name of the purchaser, said address of the

purchaser, said drug prescribed, said quantity of said drug, said dosage of said drug, said pharmacist name, and said doctor name.

Denny discloses searching the pharmaceutical data based on said drug prescribed (col. 11, lines 21-43 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Denny within Cunningham. The motivation for doing so would have been to determine whether the prescription has been filled (col. 11, lines 13-20 of Denny).

Insofar as the claim recites "one or more of," it is immaterial whether or not the other elements are also disclosed.

(H) Referring to claim 9, Cunningham discloses storing via the computer system the pharmaceutical data related to whether a request for filling a prescriptive medication is filled or declined (col. 3, lines 54-67 of Cunningham).

(I) Referring to claim 10, Cunningham discloses providing that at least one of said plurality of entities comprises a government agency (col. 2, lines 54-59 of Cunningham).

(J) Referring to claim 22, Cunningham discloses a method for controlling a computer system for tracking prescriptive medications, to address and control prescription drug abuse, the computer system comprising a processor and a connection between the processor and a plurality of entities, the entities having pharmaceutical data related to prescriptive medication purchases by a plurality of purchasers from a time of the

connection between the processor and the entity, said method comprising (abstract, Fig. 1, and col. 3, lines 54-56 of Cunningham);

providing connections from the processor to the plurality of entities, said plurality of entities being a group consisting essentially of a plurality of hospitals, a plurality of doctors, at least one government agency, or combinations thereof (Fig. 1, col. 4, lines 37-62, and abstract of Cunningham);

obtaining and storing the pharmaceutical data relating to prescriptive medication purchases by the plurality of purchasers from a plurality of pharmacies (col. 2, line 64 – col. 3, line 10 and col. 3, lines 40-67 of Cunningham; the Examiner interprets “patients” to be a form of “purchasers”);

selectively transferring said pharmaceutical data through said connections to at least one of said plurality of entities for obtaining a prescriptive history of purchaser based on said transferred pharmaceutical data (col. 3, lines 4-10 and col. 3, lines 54-67 of Cunningham).

Cunningham does not expressly disclose a complete prescriptive history that comprises all prescriptive medications purchased in the aggregate by the purchaser from all of said plurality of pharmacies and generating from said complete prescriptive history of the purchaser one or more patterns which flag prescriptive drug abuse.

Denny discloses a complete prescriptive history that comprises all prescriptive medications purchased in the aggregate by the purchaser from all of said plurality of pharmacies and generating from said complete prescriptive history of the purchaser one

or more patterns which flag prescriptive drug abuse (Fig. 7, col. 3, lines 20-37, col. 4, lines 30-46, col. 6, lines 37-51, and col. 11, line 58 - col. 12, line 20 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

6. Claims 23 and 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Denny (US 6,687,676 B1), and further in view of Edelson et al. (5,737,539).

(A) Referring to claims 23 and 24, Cunningham and Denny do not expressly disclose wherein the one or more patterns from the complete prescriptive history indicate prescription duplication, multi-source prescription abuse, or combinations thereof.

Edelson discloses wherein the one or more patterns from the complete prescriptive history indicate prescription duplication, multi-source prescription abuse, or combinations thereof (col. 27, lines 32-54 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson within Cunningham and Denny. The motivation for doing so would have been to control abuse by refusing to process the prescription (col. 27, lines 32-54 of Edelson).

Affidavits

7. Applicant has requested that the Examiner consider additional evidence of non-obviousness. In particular, Applicant relies on an affidavit filed under 37 CFR 1.132 as evidence of long felt need, inoperability of references, and unexpected results.

The affidavit under 37 CFR 1.132 filed 10/30/09 is insufficient to overcome the rejection of claims 1-4, 6-10, and 22-24 based upon the Cunningham, Denny, and Edelson references as set forth in the last Office action because:

(i) It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

(ii) The affidavits and response do not sufficiently show that the long-felt need must not have been satisfied by another before the invention by Applicant. *Newell Companies v. Kenney Mfg. Co.*, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). In fact, the teachings of the applied references, Cunningham, Denny, and Edelson, clearly demonstrate a solution to the long felt need presented in the affidavits and purported by Applicant, as their collective teachings are directed to providing a prescription history

and preventing drug abuse, having each element presently claimed. Moreover, what is construed by the Applicant as evidence of a long felt need is respectfully submitted by the Examiner to be further motivation that existed in the art prior to Applicant's invention for turning to the teachings of Cunningham, Denny, and Edelson.

(iii) It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. For example, the affidavit refers to preventing a doctor from prescribing medication to certain patients, a feature not in the claims. See MPEP § 716.

(iv) As per the affidavit of Jesse J. Bornfreund and Jeffery A. Anon, it is respectfully submitted that the affidavit is insufficient to overcome the grounds of rejection given in the previous Office Action because it appears to be self-serving in that the affidavit merely provides statements made by the named inventors. As such, the Examiner is not sure how much weight can be attributed to such statements, as they are neither positively and definitely confirmed or corroborated by other third parties/objective affiant(s), for the reasons set forth above, and because no other forms of hard evidence (i.e., graphs, charts, sample survey forms, official survey results) have been provided to evidence the averred statements.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

8. Applicant's arguments filed 10/30/09 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 10/30/09.

(1) Applicant argues that Cunningham does not teach a system adapted for preventing prescriptive drug abuse and instead describes a system used to track product media, i.e. tracking a clinical trial and/or sample pharmaceutical products.

(2) Applicant argues that Cunningham does not disclose or suggest obtaining a complete prescription history. Cunningham further fails to teach or suggest generating patterns that flag prescriptive drug abuse.

(A) As per the first argument, the Examiner respectfully submits that Cunningham is not limited to trial products. Note col. 3, lines 54-56 of Cunningham which discloses that the invention can be used for actual prescribed pharmaceuticals that are past the trial stage. Cunningham also discloses that "in order to help combat prescription *fraud*, new systems must be developed that allow prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs...." (see col. 2, lines 55-59 of Cunningham). In addition, Cunningham's initialization process (see Fig. 5) and tracking of refills is a way of determining prescription abuse. Cunningham teaches that a "patient is precluded from securing additional refills without

a new prescription" (see col. 3, lines 53-67 of Cunningham). Cunningham also teaches that "a wide variety of reports can be generated from the database" and that the database will possess a full record of all transactions (see col. 11, line 66 – col. 12, line 21).

(B) As per the second argument, the Examiner respectfully submits that Denny was relied upon in the rejections above to teach a complete prescriptive history and generating patterns that flag prescriptive drug abuse. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Nevertheless, the Examiner respectfully submits that Cunningham discloses that "prescriber and pharmacy transactions are all monitored and recorded by the central computing station" (see col. 6, lines 53-55 of Cunningham). Furthermore, Cunningham discloses a database for storing data and information communicated to the central computing station (see col. 4, lines 40-44 of Cunningham). The Cunningham system "manages, tracks, and records selected transactions involving the participating prescribers, pharmacies and patients" (see col. 3, lines 4-10 of Cunningham). Moreover, the claim does not specify the extent of the prescriptive history. For example, is it a complete prescription history of that day, month, year, lifetime, etc? As such, the

broadest reasonable interpretation of "a complete prescriptive history" would include the recording of prescription transactions disclosed in Cunningham.

Furthermore, the Examiner gave each term the broadest reasonable interpretation in light of the Applicant's specification. The Examiner referred to the specification, but was unable to find any definitions of "abuse" and "patterns" given with precision, clarity, and deliberateness to warrant the meanings currently argued by Applicant. Moreover, words of the claim are generally given their ordinary and customary meaning, unless it appears from the written description that they were used differently by the Applicant. Where an Applicant chooses to be his or her own lexicographer and defines terms with special meanings, he or she must set out the special definition explicitly and with "reasonable clarity, deliberateness, and precision" in the disclosure to give one of ordinary skill in the art notice of the change. See *Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 273 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP § 2111.01. Pursuant to 35 USC § 112, 2nd paragraph "[i]t is Appellant's burden to precisely define the invention, and not the [examiner's]." *In re Morris*, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997). Therefore, it would **not** be proper for the examiner to give words of the claim special meaning when no such special meaning has been defined by the Applicant in the written description.

For example, regarding "abuse," Applicant merely recites that "All of these entities can have immediate access to potential medication abuse by identification of

needless prescription duplications, potential drug interactions, and multi-source interstate prescriptive medication abuse" (page 24, lines 1-3 of Applicant's specification). As for the term "patterns," the specification is devoid of an explanation. For these reasons, Applicant's claims were given their broadest reasonable interpretation consistent with the specification, and the Examiner applied prior art accordingly.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./
Examiner, Art Unit 3686
In
1/8/10

/Gerald J. O'Connor/
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